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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,116	07/14/2000	Manish Aghi	0609.4830001/JAG/KRM	5851

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EXAMINER

NGUYEN, QUANG

ART UNIT PAPER NUMBER

1636

DATE MAILED: 02/08/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/617,116

Applicant(s)

AGHI ET AL.

Examiner

Quang Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-3 and 5-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Applicants' amendment filed November 29, 2001 in Paper No. 7 has been entered.

Claims 1-3 and 5-13 are pending in the present application.

Due to the clarification of "a vector for gene delivery" contemplated by Applicants for the presently claimed invention in the amendment in Paper No. 7, the following election/restrictions is required.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 5-13, drawn to a method for killing neoplastic cells utilizing a vector for gene delivery, wherein said vector comprising a nucleotide molecule encoding FPGS and said vector for gene delivery is a viral or non-viral vector, classified in class 514, subclass 44.

II. Claims 1-3, 5-6, 11 and 13, drawn to a method for killing neoplastic cells utilizing a vector for gene delivery, wherein said vector comprising a nucleotide molecule encoding FPGS and said vector for gene delivery is an endothelial cell, classified in class 424, subclass 93.2.

III. Claims 1-3, 5-6, 11 and 13, drawn to a method for killing neoplastic cells utilizing a vector for gene delivery, wherein said vector comprising a nucleotide molecule encoding FPGS and said vector for gene delivery is a macrophage, classified in class 424, subclass 93.2.

Claims 1-3, 5-6, 11 and 13 link inventions I-III. The restriction requirement between linked inventions is subject to the nonallowance of the linking claim(s), claims

1-3, 5-6, 11 and 13. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-132 (CCPA 1971). See also MPEP 804.01.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Methods cited in inventions in I-III which utilize a viral or non-viral vector, an endothelial cell and a macrophage, respectively, lack unity of invention. There is no common substantial structural feature among a viral or non-viral vector with an endothelial cell, or with a macrophage or between an endothelial cell and a macrophage. The methods comprise materially distinct processing steps and require different technical considerations for delivering into neoplastic cells a vector for gene delivery in the forms of a viral or non-viral vector or in

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the form of an endothelial cell or a macrophage, and that they are not required one for the other.

Because these inventions are distinct for the reasons set forth above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the claims in a single application. Therefore, restriction for examination purposes as indicated is proper.

Should Group I be elected, claims 1-3, 5-6, 10, 11 and 13 are generic to a plurality of disclosed patentably distinct species comprising the following species:

a prokaryotic vector, a cationic liposome, a fusogenic liposome, a DNA-adenovirus conjugate, a DNA-protein complex, a non-viral T7 autogene vector, a starburst polyamidoamine dendrimer, a cationic peptide and a mammalian artificial chromosome.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed named species as listed above, even though this requirement is traversed (37 CFR 1.143).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Additionally, claims 1-3, 5-9 and 13 are generic to a plurality of disclosed patentably distinct species as listed in claim 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed named species as indicated above, even though this requirement is traversed (37 CFR 1.143).

Should Applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.


DAVE T. NGUYEN
PRIMARY EXAMINER

Quang Nguyen, Ph.D.